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ENCLOSURE - G
510(k) for Multi-Centrifuge

SAFETY AND EFFECTIVENESS STATEMENT

A reasonable literature search has been performed to determine pertinent issues related to safety and effectiveness. All available information points to concerns with regards to centrifuges and centrifuge techniques. There were no references to electronically controlled manual hematocrit readers. In reviewing this information, the Multi-Centrifuge as a centrifuge does not raise new questions or concerns with regards to safety and effectiveness. A comparison chart between the Multi-Centrifuge and the Hematostat C-70 illustrate the areas of concerns for safety and potential areas of hazard discussed in the literature search.

CONCERNS	MULTI-CENTRIFUGE	HEMATOSTAT C-70
Hematocrit Tube Cover	Yes	No
Aerosol Hazard Eliminated	No	No
Explosion Hazard Eliminated	No	No
Bio-Hazard Eliminated	No	No
Chemical Hazard Eliminated	No	No
Door Lock	Yes	Yes
Excessive Fiction Hazard	Yes	No
Low Power	Yes	No
Out of balance Hazard	Yes	Yes

Although, there is no information with regards to manual hematocrit readers, the Multi-Centrifuge and Hematostat C-70 differ in one area; angle factor. Both hematocrit readers utilize various distances to calculate a ratio (Hct) of Red Blood Cells to blood sample volume. These distances are at key separation (interface) points marked by the user. This is similar to marking distances with a ruler. Using a flat disk rotor, the interface points run perpendicular to the hematocrit tube length. These marked interface points are as follows:

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1. Sealant/Red Blood Cells. This is Point A or the starting point for the packed red blood cells and blood sample volume.
2. Red Blood Cells/Plasma. This is Point B or the ending point for the packed red blood cells.
3. Plasma/Air. This is Point C or the ending point for the blood sample volume.

Once these areas are marked by the user, the microprocessor uses the following equation to calculate the ratio:

$(A + B) / (A + C) \times 100 = XX.X\%$

An example of a basic calculation once areas are marked is as follows:

A = 0
B = 1 inch
C = 2 inch

$(0 + 1) / (0 + 2) \times 100 + 50.0\%$

However, the Hematostat C-70 has an addition "angle factor (Af)" added to the equation. $(A + B) / (A + C) \times ff \times 100\% = XX.X\%$. This angle factor is needed to account for the angle at which the various interface points occurs. This angle is the result of the 70° fixed angle Hct rotor used by the Hematostat. As blood separation occurs in the Hematostat C-70, the interface points also have a 70° angle. Because of this and the small LCD display, this makes it difficult and leads to potential inconsistencies for the user when marking each interface point. Because the Multi-Centrifuge uses a flat disk rotor, all interface points are perpendicular to the hematocrit tube. This and a larger LCD display provides ease of use and consistency.

The Multi-Centrifuge poses no increase risk to safety or diminishes effectiveness of use. This device does not raise any new or additional concerns for use. Further, the hematocrit reader offers a simpler linear algorithmic equation for Hct determination.

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